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1490

Product Information

Always

Robins—Cont.

Adverse Reactions: Rarely, nausea, gastrointestinal upset, constipation, and drowsiness may occur. No serious side effects from guaiacolamine have been reported.

Dosage: Adults and children 12 years of age and over: 2 teaspoonsful every four hours, not to exceed 12 teaspoonsfuls in a 24 hour period; children 6 to under 12 years: 1 teaspoonful every four hours, not to exceed 6 teaspoonsfuls in a 24 hour period; children 3 to under 6 years: $\frac{1}{2}$ teaspoonful every four hours, not to exceed 3 teaspoonsfuls in a 24 hour period; children under 2 years: use as directed by physician.

How Supplied: Bottles of 3 ounces (NDC 0031-8874-05), 4 ounces (NDC 0031-8874-12), one pint (NDC 0031-8874-25), and one gallon (NDC 0031-8874-29).

ROBITUSSIN-DAC

SKELAXING TABLETS

Z-BECG

One tablet daily prevent.

Pain

U.S. No.

Vitamin

Composition

Vitamin E

Vitamin C

Thiamine

(Vitamin B₁)

Riboflavin

(Vitamin B₂)

Niacin

Vitamin B₆Vitamin B₁₂

Pantothenic Acid

Mineral

Composition

Boric

"22.5 mg zinc (equivalent

ing Zinc Sulfate, USP)

Ingredients: Salicylate

mide; Zinc Sulfate; Vi-

cium Pantothenate; L-

Methylcellulose; Pow-

dered Starch; Thiamine

Color; Pyridoxine Hy-

dride; Silica; Propylene Gly-

colamine.

Actions and Uses:

formulation. Its com-

roles in general nutriti-

and prevention of inci-

pitated for deficiency

conditions such as fa-

acute infections, burns,

trauma, toxic conditions,

coagulation, prolonged ex-

treme, gout, gouty arthri-

tis; and in conditions

and weight-reducing.

In dentistry, Z-BECG

tinctives of uncomplicated

herpetic stomatitis, at-

trophic, herpangina and

Precautions:

Not indicated.

of pernicious anemia.

Dosage:

The recommended dose

for adults and children 12

years of age, other than pre-

natal, is one tablet daily with

water or juice.

Under the direction of a

physician, the dose and fre-

quency may be increased in

the patient's requirements.

How Supplied:

Green

shaped tablets in bottles

of 100 (NDC 0031-8874-01)

[Shown in Product

Each 5 ml (1 teaspoonful) contains:

Guaiacolamine, USP 100 mg

Pseudoephedrine

Hydrochloride, USP 30 mg

Cocaine Phosphate, USP 10 mg

(Warning: May be habit forming)

In a palatable, aromatic syrup

Alcohol 1.4 per cent

Indications: For the temporary relief of cough and nasal congestion as may occur with the common cold or with inhaled irritants.

Contains the expectorant, guaiacolamine, which relieves irritated membranes in the respiratory passageways by preventing dryness through increased mucus flow. The nasal decongestant, pseudoephedrine, reduces the swelling of nasal passageways. The antitussive, cocaine, calms the cough control center and relieves coughing.

Contraindications: Hypersensitivity to any of the ingredients, marked hypertension, hyperthyroidism, or in patients who are receiving MAO inhibitors or antihypertensive medication.

Warnings: Use this product with caution in children under 3 years or in children taking another drug. Prescribe cautiously for patients with persistent or chronic cough such as comes with smoking, asthma, emphysema, or where cough is accompanied by excessive secretions. Caution should be taken in administering this drug to patients with high blood pressure, heart disease or diabetes. In patients with chronic pulmonary disease or shortness of breath, this product should be administered with caution. As with all products containing sympathomimetic amines, use with caution in patients with prostatic hypertrophy or glaucoma. Do not exceed recommended dosage because at higher doses nervousness, dizziness or sleeplessness may occur. May cause or aggravate constipation.

Note: Guaiacolamine has been shown to produce a color interference with certain clinical laboratory determinations of 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

Adverse Reactions: Agitation, dizziness, tachycardia, palpitations or nervousness may occur. In such instances, reduction in frequency and/or quantity of dose is indicated.

Revised Dosage: Adults and children 12 years of age and over: 1 or 2 teaspoonsfuls every six hours, not to exceed 8 teaspoonsfuls in a 24-hour period; children 6 to under 12 years: 1 teaspoonful every six hours, not to exceed 4 teaspoonsfuls in a 24-hour period; children 3 to under 6 years: $\frac{1}{2}$ teaspoonful every six hours, not to exceed 2 teaspoonsfuls in a 24-hour period; children under 2 years: use as directed by physician.

How Supplied: Robitussin-DAC is available in pints (NDC 0031-8880-25).

Precautions: Elevations in cephalin flocculation tests without concurrent changes in other liver function parameters have been noted. Hence, it is recommended that metaxalone be administered with great care to patients with pre-existing liver damage and that serial liver function studies be performed as required.

False-positive Benedict's tests, due to an unknown reducing substance, have been noted. A glucose-specific test will differentiate findings.

Pregnancy: Reproduction studies have been performed in rats and have revealed no evidence of impaired fertility or harm to the fetus due to metaxalone. Reactions reports from marketing experience have not revealed evidence of fetal injury, but such experience cannot exclude the possibility of infrequent or subtle damage to the human fetus. As with all drugs, metaxalone should be used in women who are or may become pregnant only when clearly needed.

Nursing Mothers: It is not known whether this drug is secreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

Pediatric Use: Safety and effectiveness in children 12 years of age and below have not been established.

Adverse Reactions: The most frequent reactions to metaxalone include nausea, vomiting, gastrointestinal upset, drowsiness, dizziness, headache, and nervousness or "irritability." Other adverse reactions are: hypersensitivity reaction, characterized by a light rash with or without pruritus; leukopenia; hemolytic anemia; jaundice.

Dosage: The recommended dose for adults and children over 12 years of age is two tablets (800 mg) three to four times a day.

Management of Overdosage: Gastric lavage and supportive therapy as indicated. (When determining the LD₅₀ in rats and mice, progressive sedation, hypnosis and finally respiratory failure were noted as the dosage increased. In dogs, no LD₅₀ could be determined as the higher doses produced an erratic action in 15 to 20 minutes). No documented case of major toxicity has been reported.

How Supplied: Stolazin (metaxalone) is available as a 400 mg, pale rose tablet (scored), in bottles of 100 (NDC 0031-8034-01).

Importance

Before prescribing

any product

PHARMACEUTICAL

always consult the PDR

possible new or unde-